REMARKS

Reconsideration of the application is respectfully requested.

I. Status of the Claims

Claims 1 - 3, 8 and 9 are currently pending, with claims 4 - 7 having been previously canceled. Claim 9 is found by the Examiner as being drawn to an unelected invention as defined by a previous restriction requirement, and is withdrawn.

With this Response, claims 1, 3, 8 and 9 are amended. No new matter is introduced.

II. Rejections under 35 U.S.C. § 112

Claim 8 is rejected under the first paragraph of 35 U.S.C. § 112 as failing to comply with the written description requirement. Specifically, the Examiner suggests that the specification fails to teach that the reporting unit reports a trouble condition for the blood purifier when the difference between the first measurement value and the first theoretical value is approximately equal to the difference between a second measurement value and a second theoretical value.

Applicants amend claim 8 to provide that the trouble condition is reported for the blood purifier when the calculating and evaluation units determine that a difference between a second measurement value and a second theoretical value for an adjusted blood flow rate is determined to be larger than a second predetermined acceptable ratio difference. Support for amended claim 8 may be found, for example, with reference to Applicants' specification at page 12, line 24 through page 15, line 10.

Accordingly, Applicants respectfully request that the rejection of claim 8 under the first paragraph of 35 U.S.C. § 112 be withdrawn.

II. Rejections under 35 U.S.C. § 103

Claims 1 - 3 and 8 are rejected under 35 U.S.C §102(a) as being anticipated by, or in the alternative, rejected under 35 U.S.C §103(a) as being unpatentable over Brugger et al. (U.S. Patent No. 6,554,789, herein "Brugger). Applicants amend claims 1, 3 as to informalities, amend claim 8 to overcome the above-described rejection under the first paragraph of 35 U.S.C. § 112, and respectfully traverse the rejections of claim 1 - 3 and 8 under 35 U.S.C §102(a) based on Brugger.

In amended independent claim 1, Applicants claim:

1. A blood purification device comprising:

a blood circuit having an arterial blood circuit and a venous blood circuit;

a blood pump disposed in said arterial blood circuit;

a blood purifier connected to the blood circuit between said arterial blood circuit and said venous blood circuit, and configured to purify blood flowing in said blood circuit;

a first measuring unit disposed in said arterial blood circuit and configured to measure a blood concentration of said arterial blood circuit;

a second measuring unit disposed in said venous blood circuit and configured to measure a blood concentration of said venous blood circuit;

a calculating unit configured to calculate a first measurement value and a first theoretical value, said first measurement value referring to a ratio of said blood concentrations measured by said first measuring unit and said second measuring unit, and said first theoretical value referring to a blood concentration ratio obtained by at least one formula based on parameters including a preset blood flow rate of said blood pump and a preset blood purifying rate of said blood purifier;

an evaluation unit configured to evaluate whether a difference between said first measurement value and said first theoretical value is larger than a first predetermined acceptable ratio difference; and

a reporting unit configured to report a trouble condition for at least one of said blood pump and said blood purifier when the difference between said first measurement value and said first theoretical value is larger than the predetermined acceptable ratio difference.

Brugger discloses a layered fluid circuit for purifying blood (see, e.g., abstract and Col. 9: 24 - Col. 10: 24 of Brugger). The device of Brugger includes a blood pump and blood purifier (see, e.g., Col. 5: 58 - 65), and upstream and downstream hematocrit sensors for sensing pre- and post-treatment blood concentrations (see, e.g., Col. 24: 8 - 34). Brugger teaches a device that periodically measures the difference between pre- and post-treatment hematocrit levels, and determines a fluid reduction ratio based on a current blood flow rate and the measured difference (see, e.g., Col 24: 21 - 34). When the determined fluid reduction ratio differs from a desired ratio, Brugger's device adjusts a flow restrictor to eliminate the difference.

In amended independent claim 1, Applicants claim a device that measures pre- and post-treatment blood concentrations to perform a very distinct function from the flow rate control function performed by the device of Brugger. Specifically, Applicants' claimed device includes a calculating unit, an evaluation unit and a reporting unit configured to perform the following functions. The calculating unit calculates a first measurement value that is represented by a ratio of the blood concentrations measured by first and second measuring units, and calculates a first theoretical value for this ratio based on a current flow rate of the blood pump and a current purifying rate of the blood purifier. The evaluation unit then evaluates whether the difference between the measured ratio of blood concentrations and theoretical ratio of blood concentrations is

larger than a predetermined acceptable difference. In the event that the measured difference exceeds the acceptable difference, the reporting unit reports a trouble condition identifying that at least one of the blood pump and the blood purifier is malfunctioning.

Thus, and in sharp contrast to the device disclosed by Brugger, the invention claimed by Applicants is directed to detecting and reporting a trouble condition indicating that at least one of the blood pump or blood purifier is malfunctioning at a predetermined performance rate, rather than providing a mechanism like Brugger for adjusting a flow rate to achieve a desired fluid removal rate. While Brugger's device provides for detecting and reporting an unsafe operating condition (see, e.g., Col. 31: 9 - 15), Brugger nowhere describes or otherwise suggests Applicants' claimed mechanisms for detecting and reporting a malfunction of the blood pump or blood purifier. Applicants' claimed mechanisms provide the advantage of simplifying over prior art systems requiring, for example, additional pressure sensors to detect a degradation in the performance of one or more of the blood pump and blood purifier.

The Examiner acknowledges that Brugger fails to expressly teach Applicants' claimed evaluation unit for evaluating whether a difference between a measured ratio of blood concentrations and a theoretical ratio of blood concentrations is larger than a predetermined acceptable difference, and fails to expressly teach Applicants' claimed. reporting unit for reporting a trouble condition identifying that at least one of the blood pump and the blood purifier is malfunctioning. The Examiner however finds that it would have been obvious to one skilled in the art at the time of Applicants' invention to modify Brugger to include these claimed features. Applicants respectfully disagree.

As described above, Brugger teaches a layered fluid circuit for purifying blood that may include upstream and downstream hematocrit sensors for sensing pre- and post-treatment blood concentrations. Brugger describes these sensors as having only a single purpose: providing pre- and post-treatment hematocrit levels for periodically deriving a fluid reduction value, which is compared to a desired fluid reduction value in order to adjust a flow restrictor for controlling the fluid flow rate (see, e.g., Col. 24: 21 - 34). Brugger nowhere teaches or suggest a use for the hematocrit sensors in judging a trouble condition of the device.

The Examiner suggests that, because Brugger teaches reporting leaks and other trouble conditions, it would have been obvious to one skilled in the art at the time of the invention to modify the device of Brugger for reporting such trouble conditions. Applicants respectfully disagree. While Brugger suggests that leaks and other trouble conditions for the device can be reported, Brugger clearly suggests other means for detecting and reporting these conditions than the means claimed by Applicants. For example, as to leaks, Brugger describes air sensors for detecting air leaks in the arterial and venus blood paths (see, e.g., Col. 10: 10 - 23 of Brugger) and a blood leak detector in the blood waste path (see, e.g., Col 10: 41 - 47 of Brugger). Applicants' claimed invention eliminates the need for these specialized leakage detectors as taught by Brugger by configuring calculating and evaluation units that detect leaks and other troubles associated with the blood pump and blood purifier by measuring an actual blood concentration ratio and determining a deviation of this ratio from a theoretical value, and by configuring a reporting unit that reports a trouble condition when the deviation exceeds a predetermined acceptable ratio difference. Arguably, by disclosing specialized sensors for detecting leaks in the fluid flow paths, Brugger teaches away from Applicants' claimed approach.

Accordingly, Applicants respectfully submit that Applicants' purification device as claimed in amended independent claim 1 is neither anticipated nor made obvious by Brugger, and stands in condition for allowance. As claims 2, 3 and 8 depend from allowable independent claim 1, Applicants submit that claims 2, 3 and 8 are also allowable for at least this reason.

For the above-argued reasons, Applicants respectfully request that the rejections of claims 1 - 3 and 8 under 35 U.S.C §103(a) be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

The Examiner is respectfully requested to contact the undersigned at the telephone number indicated below if the Examiner believes any issue can be resolved through either a Supplemental Response or an Examiner's Amendment.

Dated: August 21, 2007

Respectfully submitted,

By _____
Thomas J. Bean
Registration No.: 44,528
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant